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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,257	04/27/2007	Nobukazu Tanaka	286669US0PCT	2219

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EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/576,257	**Applicant(s)** TANAKA ET AL.	
	Examiner ADAM MILLIGAN	**Art Unit** 1612	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-13 and 16-19*.
   Claim(s) withdrawn from consideration: *14 and 15*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/ADAM MILLIGAN/
Examiner, Art Unit 1612

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1-12 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to English equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464).
First, Applicants assert that Masaki states that "A structural body having desired hardness and disintegration rate can be obtained regardless of the mixing ratio". Second, Applicants point out that some of the blending ratios taught in Masaki fall outside the scope of the instant climes and provide nothing with respect to having an excellent balance of disintegration time and tabletting properties. Third, Applicants point to their data and claim it demonstrates unexpected results. Applicants argue that the difference in tabletting pressure in the data relied upon is a non-issue because the tabletting pressure is varied in order to produce tablets having the same hardness.
Examiner disagrees. The general statement pointed to by Applicants only refers to the fact that the prior art teaches that a variety of mixture can have sufficient hardness and disintegration time. This statement in no way implies that every formulation having a combination of lactose and/or mannitol will have equal hardness and disintegration time. In fact, tables 1 (col.9) and 6 (col. 12) demonstrate that the disintegration time varies with the ratio of mannitol to lactose. Using this data as a basis, the skilled artisan would find it obvious to optimize the ratio mannitol to lactose in order to achieve the minimum disintegration time.
Second, the fact that some of the examples described by Masaki are outside of the claimed range does not negate the broader teaching of Masaki. Masaki is relied on for the broader teaching that disintegration time varies with the ratio of mannitol to lactose. The skilled artisan aware of Masaki would find it obvious to run routine tests on tablets containing various ranges of mannitol to lactose to find the minimal disintegration time., as demonstrated by the disclosure of Masaki
Third, While tabletting pressure is disclosed, the resulting hardness is not. As such, it is unclear from the evidence provided whether the resulting tablets all share a common hardness or not. Without such evidence, the Examiner is unable to determine if Applicants assertion of improved tablet characteristics is sufficient to overcome the obviousness rejection
Further, Examiner asserts the results are not unexpected, even if the tablets are the same hardness, given the disintegration time of the claimed range falls within comparative examples A and D.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to english equivalent document U.S. 2004/0033258) in view of Masaki (U.S. 5,466,464), The combination further in view of Ishikawa (Preparation of Rapidly Disintegrating Tablet Using New Types of Microcrystalline Cellulose (PH-M Series) and Low Substituted-Hydroxypropylcellulose or Spherical Sugar Granules by Direct Compression Method, Chem. Pharm. Bull., Vol.49, No.2, pp.134-139, 2001).
All arguments are presented together and discussed above. For the reasons stated above, this rejection is maintained.

Claims 1-13 and 16-19 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-28, and 30-32 of copending Application No. 10/945,049.
Applicants state that when no other rejections exist, it may be appropriate according to MPEP 822.01, to withdraw the rejection and permit the application to issue as a patent , thereby converting the provisional double patenting rejection in the other application into a double patenting rejection.
Here, since a obviousness rejection remains as discussed above, Applicants arguments are not applicable at this time. Accordingly, this rejection is maintained.